UNITED STATES DISTRICT COURT
DISTRICT OF NEW MEXICO

DEBORAH CARR,

Plaintiff,

v. **No. 1:22-cv-00592**

BOSTON SCIENTIFIC CORPORATION and COLOPLAST CORPORATION,

Defendants.

COMPLAINT FOR DAMAGES AND JURY DEMAND

Plaintiff DEBORAH CARR ("Plaintiff") files this Complaint and for causes of action against Defendants BOSTON SCIENTIFIC CORPORATION ("BSC") and COLOPLAST CORPORATION ("Coloplast") alleges as follows:

INTRODUCTION

1. On or about August 29, 2019, Plaintiff DEBORAH CARR was surgically implanted with a Boston Scientific Obtryx II Halo System (the "Obtryx") as well as a Coloplast Restorelle Y Mesh product ("Y Mesh"), pelvic mesh products and medical devices designed, manufactured, and marketed by Defendants BSC and Coloplast, respectively.

2. Although the Obtryx was intended to treat stress urinary incontinence, and the Y Mesh was intended to serve as part of a surgical treatment for vaginal vault prolapse, neither Plaintiff nor her healthcare providers were warned that these Pelvic Mesh Products were defective and negligently designed and manufactured. As a result of being surgically implanted with Defendants' unreasonably dangerous defective Pelvic Mesh Products, Plaintiff has suffered, and

continues to suffer, debilitating injuries, as described further herein. Plaintiff brings this suit for damages related to those injuries.

JURISDICTION AND VENUE

3. The Court has jurisdiction over this civil action pursuant to 28 U.S.C. § 1332(a) inasmuch as the amount in controversy exceeds $75,000 and the Plaintiff is a citizen of a different state than the Defendants.

4. Venue in this district for pretrial proceedings in these civil actions is proper under 28 U.S.C. § 1391, inasmuch as a substantial part of the events or omissions giving rise to the claim occurred in this district. Specifically, Plaintiff was implanted with the products at issue at the in this district at the Lovelace Women's Hospital in Albuquerque, New Mexico, and was injured in this district.

5. Defendants are subject to *in personam* jurisdiction in the U.S. District Court for the District of New Mexico because Defendants placed defective products in the stream of commerce and all or some of those products were implanted into and caused personal injuries to Plaintiff, a New Mexico resident, in the State of New Mexico. Each Defendant has sufficient minimum contacts in New Mexico or otherwise intentionally avails itself of the New Mexico market through, without limitation, its advertisement, promotion, marketing, sales and/or distribution and other business activities, so as to render the exercise of jurisdiction over it by the New Mexico courts consistent with traditional notions of fair play and substantial justice.

PARTIES

6. Plaintiff DEBORAH CARR is a citizen and resident of New Mexico who was implanted with Defendants' defective medical devices at the Lovelace Women's Hospital in Albuquerque, New Mexico.

7. Defendant Boston Scientific Corporation is a Massachusetts corporation with its principal place of business in Massachusetts.

8. Defendant Coloplast Corporation is a corporation organized and existing under the laws of the State of Delaware, maintaining its principal place of business at 1601 West River Road North, Minneapolis, Minnesota 55411.

9. At all times material hereto, Defendants were engaged in the business of developing, manufacturing, licensing, promoting, marketing, distributing, testing, warranting and/or selling in interstate commerce throughout the United States, including New Mexico, either directly or indirectly, their medical devices intended to treat stress urinary incontinence and/or pelvic organ prolapse, including the BSC Obtryx and Coloplast Y Mesh products that were implanted into Plaintiff.

10. Defendants are vicariously liable for the acts and omissions of its employees and/or agents who were at all times relevant hereto acting on behalf of the Defendants and within the scope of their employment or agency with the Defendants.

11. At all times relevant herein, the Defendants were engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, testing, training, marketing, promoting, packaging, labeling, and/or selling such devices, including the Obtryx and Y Mesh pelvic mesh products. Defendants manufacture, market, advertise, promote, and sell these products worldwide.

FACTUAL BACKGROUND

The Pelvic Mesh Products

12. At all times relevant herein, Defendants were engaged in the business of developing, designing, licensing, manufacturing, distributing, marketing, packaging, labeling,

advertising delivering, selling and introducing into interstate commerce, including within the United States and within the State of New Mexico, either directly or indirectly through third parties or related entities, a line of pelvic mesh products (the "Pelvic Mesh Products"), including the Obtryx and Y Mesh products, the devices implanted into Plaintiff. The Obtryx product was designed primarily for the purpose of treating stress urinary incontinence; the Y Mesh product was designed primarily as a "bridging material" for the surgical treatment for vaginal vault prolapse. All references herein to Pelvic Mesh Products includes the Obtryx and Y Mesh pelvic mesh products.

13. A pelvic organ prolapse ("POP") occurs when a pelvic organ, such as the bladder, drops ("prolapses") from its normal position and pushes against the walls of the vagina. Prolapse can happen if the muscles that hold the pelvic organs in place become weak or stretched from childbirth or surgery. More than one pelvic organ can prolapse at the same time. Organs that can be involved in a pelvic organ prolapse include the bladder, the uterus, the bowel and the rectum. At all relevant times, the Y Mesh was intended to be used, and for Plaintiff was used, to pelvic organ prolapse.

14. Stress urinary incontinence ("SUI") is a type of incontinence characterized by leakage of urine during moments of physical stress, such as coughing, laughing, or sneezing. Although inconvenient, SUI is not life threatening. At all relevant times, the Obtryx was intended to be used, and for Plaintiff was used, to treat stress urinary incontinence.

15. Surgical mesh is a medical device that is generally used to repair weakened or damaged tissue. This is the type of mesh used in Defendants' Pelvic Mesh Products, including the Obtryx and Y Mesh pelvic mesh products at issue in this case. In urogynecologic procedures, surgical mesh is permanently implanted to reinforce the weakened vaginal wall to repair POP or

to support the urethra to treat SUI. Most pelvic mesh products, including the Obtryx and Y Mesh pelvic mesh products at issue in this case, are comprised of non-absorbable, synthetic, monofilament polypropylene mesh. The Pelvic Mesh Products, including the Obtryx and Y Mesh pelvic mesh products, were and are specifically promoted to physicians and patients as an innovative, minimally invasive procedure with minimal local tissue reactions, minimal tissue trauma, and minimal pain while correcting stress urinary incontinence and pelvic organ prolapse.

16. Prior the implantation of the Obtryx and Y Mesh pelvic mesh products at issue in this claim, Defendants sought and obtained Food and Drug Administration ("FDA") approval to market the Pelvic Mesh Products under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required.

17. In 1996, the FDA cleared the first pelvic mesh products for use in the treatment of SUI. These products include products manufactured, marketed, and distributed by Defendants. These products were and are approved by the FDA under the abbreviated 510(k) approval process. No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever conducted with regard to these pelvic mesh products, including the Obtryx and Y Mesh pelvic mesh products at issue in this case.

18. Despite claims that polypropylene mesh is inert, the scientific evidence shows that this material as implanted in Plaintiff and others is biologically incompatible with human tissue, and when used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair, polypropylene and other surgical polymers promote a severe foreign body reaction and chronic

inflammatory response in a large subset of the population implanted with Defendants' Pelvic Mesh Products.

19. This "host defense response" by a woman's pelvic tissues promotes degradation of the polypropylene mesh and the pelvic tissue, and causes chronic inflammation of the pelvic tissue, shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response, and chronic pain. It also can cause new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening and anatomic deformation, and can contribute to the formation of severe adverse reactions to the mesh. Certain information was available in the medical literature regarding the dangers of polypropylene mesh and manufacturers should have been aware of this literature.

a. Shrinkage and bacteria lead to an evolving process and increased erosion (Klinge U. Eur J Surg 1998; 164:965, Jacquetin B. Int Urogyn J 2009; 20:893, Tunn R. Ultrasound Obstetrics Gynecol 2007; 29:449).

b. Polypropylene mesh has long been known to shrink (Klinge U. Eur J Surg 1998; 164:965, Jacquetin B. Int Urogyn J 2009; 20:893, Tunn R. Ultrasound Obstetrics Gynecol 2007; 29:449). By 1998, polypropylene mesh was known to shrink 30-50%. This was subsequently confirmed in 2007 (Klinge U. Eur J Surg 1998; 164:965, Jacquetin B. Int Urogyn J 2009; 20:893, Tunn R. Ultrasound Obstetrics Gynecol 2007; 29:449). Predominate infection/inflammation was noted in 2007 in explanted polypropylene samples (Yahi Y. Int Urogyn J 2007; 18(Suppl 1):S149).

c. The weave of the mesh produces very small interstices which allow bacteria to enter and to hide from the host defenses designed to eliminate them. The

bacteria can secrete an encasing slime (biofilm) which further serves to protect them from destruction by white blood cells and macrophages (Osterberg B. ActaChirScand1979; 145:431, Merritt K. J BiomatAppl 1991; 5:185, An Y. J Biomed Mater Res (ApplBiomat) 1998; 43:338).

d. The large surface area promotes wicking of fluids and bacteria which provides a safe haven for bacteria which attach themselves to the mesh during the insertion process (Mahmoud W. J Biomat Sci Polymer Ed 1996; 7:751, Klinge U. J Biomed Mater Res 2002; 63:765, Vollebregt A. Int Urogyn J 2009; 20:1345).

e. The size of the mesh placed equates to a large surface area with many places for bacteria to hide while being protected from host defenses (Mahmoud W. J Biomat Sci Polymer Ed 1996; 7:751, Klinge U. J Biomed Mater Res 2002; 63:765, Vollebregt A. Int Urogyn J 2009; 20:1345).

f. Polypropylene is impure: There is no such thing as pure polypropylene. Polypropylene contains about 15 additional compounds which are leached from the polypropylene and are toxic to tissue which enhances the inflammatory reaction and the intensity of fibrosis (Sternschuss G. J Urol 2012; May 12 epub, Frostling H. Scand J Work Environ Health 1984; 10:163).

g. Prolene (polypropylene) was shown to be not inert in 1986 and again in 2003 with flaking and fissuring demonstrated by scanning electron microscopy which leads to degradation and release of toxic compounds.

This enhances the inflammatory and fibrotic reactions (Coda A. Hernia 2003; 7:29, Jongebloed WL. Doc Ophthalmol 1986; 64:143–52).

h. With the loss of polypropylene due to degradation, the surface area is greatly increased thus providing greater areas for bacterial adherence and more elution of toxic compounds from the polypropylene and also the freed toxic polypropylene itself, all of which increases the inflammatory reaction and intensity of fibrosis (Jongebloed W. Doc Ophth 1986; 64:143, Sternschuss G. J Urol 2012; May 12 epub, Clave A. Int Urogyn J 2010; 21:261).

i. Complications from mesh placement for pelvic organ prolapse include among other adverse events: acute and chronic infection, tissue contraction due to mesh shrinkage, erosion of the mesh into adjacent structures, and dyspareunia [painful sexual intercourse]. Cosson, M., et al., Mechanical properties of synthetic implants used in the repair of prolapse and urinary incontinence in women: which is the ideal material? Int Urogynecol J Pelvic Floor Dysfunct, 2003. 14(3): p. 169-78; discussion 178. Jones, K.A., et al., Tensile properties of commonly used prolapse meshes. Int Urogynecol J Pelvic Floor Dysfunct, 2009. 20(7): p. 847-53. Margulies, R.U., et al., Complications requiring reoperation following vaginal mesh kit procedures for prolapse. Am J Obstet Gynecol, 2008. 199(6): p. 678 e1-4.

j. Erosion can be defined as the mesh wearing, or slowly grinding through the vaginal wall. This is a serious complication and moreover, there is evidence that meshes shrink in vivo leading to increased stiffness, pain and poor

restoration of the normal properties of the vagina. Dora, C.D., et al., Time dependent variations in biomechanical properties of cadaveric fascia, porcine dermis, porcine small intestine submucosa, polypropylene mesh and autologous fascia in the rabbit model: implications for sling surgery. J Urol, 2004. 171(5): p. 1970-3.

k. Larger pores within polypropylene mesh materials, allowing macrophage and leukocyte migration, reduce infection. Birch C, Fynes MM. The role of synthetic and biological prosthesis in reconstructive pelvic floor surgery. Curr Opin Obstet Gynecol. 2002; 14:527–595. 22. Govier FE, Kobashi KC, Kozlowski PM, Kuznetsov DD, Begley SJ, McGonigle KF, et al. High complication rate identified in sacrocolpopexy patients attributed to silicone mesh. J Urol. 2005;65:1099–1103.

20. BSC used Marlex® HGX-030-01 Polypropylene Homopolymer resin in its transvaginal mesh kits, both pelvic organ prolapse kits and sling systems. The Marlex® resin was manufactured by Phillips Sumika Polypropylene Company, ("Phillips") a joint venture between Chevron Phillips Chemical Company, LP, and Sumitomo Chemical.

21. Marlex HGX-030-01 resin is a polypropylene plastic that comes in the form of pellets. For several years, Phillips issued revised Material Safety Data Sheets ("MSDS") for Marlex polypropylene. Boston Scientific was aware of the Marlex MSDS at all relevant times, including when it manufactured and marketed its Products to the public, including Plaintiff and her physicians.

22. The Marlex MSDS expressly prohibits use of the material for permanent human implantation:

> MEDICAL APPLICATION CAUTION: DO NOT USE THIS CHEVRON PHILLIPS CHEMICAL MATERIAL IN MEDICAL APPLICATIONS INVOLVING PERMANENT IMPLANTATION IN THE HUMAN BODY OR PERMANENT CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES.
>
> DO NOT USE THIS CHEVRON PHILLIPS CHEMICAL COMPANY LP MATERIAL IN MEDICAL APPLICATIONS INVOLVING BRIEF OR TEMPORARY IMPLANTATION IN THE HUMAN BODY OR CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES UNLESS THE MATERIAL HAS BEEN PROVIDED DIRECTLY FROM CHEVRON PHILLIPS CHEMICAL COMPANY LP UNDER AN AGREEMENT WHICH EXPRESSLY ACKNOWLEDGES THE CONTEMPLATED USE.
>
> CHEVRON PHILLIPS CHEMICAL COMPANY LP MAKES NO REPRESENTATION, PROMISE, EXPRESS WARRANTY OR IMPLIED WARRANTY CONCERNING THE SUITABILITY OF THIS MATERIAL FOR USE IN IMPLANTATION IN THE HUMAN BODY OR IN CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES.

23. When the BSC Pelvic Mesh Products, including the Obtryx pelvic mesh product at issue in this case, are inserted in the female body according to the manufacturers' instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

24. On October 1, 2004, Phillips Sumika Polypropylene Company (PSPC) entered a one-year stand- alone indemnification/insurance agreement which waived the company's liability for Boston Scientific's decision to use the polypropylene material in medical applications. That agreement included the following language for Boston Scientific's use of the resin material in its transvaginal mesh products:

> BEFORE USING ANY PSPC POLYPROPYLENE PRODUCT, BOSTON SCIENTIFIC IS ADVISED AND CAUTIONED TO MAKE ITS OWN DETERMINATION AND ASSESSMENT OF THE SAFETY AND SUITABILITY OF THE PSPC POLYPROPYLENE PRODUCT FOR USE BY, FOR OR ON BEHALF OF BOSTON SCIENTIFIC. IT IS THE ULTIMATE RESPONSIBILITY OF BOSTON SCIENTIFIC TO ENSURE THAT THE PSPC POLYPROPYLENE PRODUCT IS SUITED TO BOSTON SCIENTIFIC'S SPECIFIC APPLICATION.

25. The 2004 Indemnity Agreement placed the burden on Boston Scientific to conduct any and all necessary testing to ensure that the product they marketed with Marlex resin was safe for its intended use.

26. Boston Scientific performed no long-term safety studies on the dangers associated with the permanent implantation of its Obtryx sling.

27. Subsequent to this 2004 indemnity agreement, in September of 2005, Phillips decided not to renew its contract with Boston Scientific because the resin was not intended for use in permanent implant devices. Per the terms of the 2004 contract between the two companies, Boston Scientific decided to exercise a right it held to make a "last-time" buyout before the contract was terminated. In 2005, BSC purchased 4,000 pounds of Marlex® HGX-030-01, the equivalent of a 10-year supply.

28. Synthetic materials like polypropylene, including that used by BSC, are known to induce an acute inflammatory response, followed by chronic inflammatory response and foreign-body reaction. A chronic inflammatory response and heightened foreign body reaction have the potential to result in failure of the device to perform safely and effectively, with significant adverse consequences for the patient. Further, a prolonged inflammatory response exposes the polypropylene mesh to a continuous bath of oxidants that may cause in vivo degradation of the mesh.

29. The polypropylene MSDS specifies that polypropylene may react with strong oxidizing agents. Despite the known warnings and complications, Boston Scientific utilized Marlex that had never been qualified by the supplier for permanent human implantation for a medical application that was disallowed according to the Material Safety Data Sheet (MSDS) in its manufacture of the Obtryx sling.

30. The polypropylene mesh used by Boston Scientific and Coloplast for their Pelvic Mesh Products also contracts as a result of the development of scar tissue exacerbated by the foreign body reaction. Polypropylene mesh is known to shrink by up to over 50% during healing. When the transvaginal mesh shrinks during the normal healing process, the arms of the mesh pull on their anchoring points in the pelvic sidewall muscles, tending to pull these anchoring points and the attached muscle toward the midline. In women with these transvaginal mesh implants, including Plaintiff herein, this pulling on the pelvic sidewall muscles causes pain at rest, during sexual intercourse, during defecation, and during normal daily activities like coughing, jumping and straining. This aggravated pulling will cause new or worsening pain to the women in whom the product is implanted. In addition, it is well established that nerves can become entrapped as a result of the chronic inflammatory response and fibrosis surrounding the mesh.

31. Defendants marketed the Pelvic Mesh Products, including the Obtryx and Y Mesh pelvic mesh products, to the medical community and to patients as safe, effective, and reliable medical devices that can be implanted by safe, effective, and minimally invasive surgical techniques.

32. Defendants marketed and sold the Pelvic Mesh Products, including the Obtryx and Y Mesh pelvic mesh products, through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies included, but are not limited to, aggressive marketing and the provision of valuable cash and non-cash benefits to healthcare providers. Defendants also utilized documents, patient brochures, and websites, offering exaggerated and misleading expectations as to the safety and utility of this product.

33. Contrary to the representations and marketing of Defendants, the Pelvic Mesh Products, including the Obtryx and Y Mesh pelvic mesh products, have high failure, injury, and

complication rates, fail to perform as intended, require frequent and often debilitating revision surgeries, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff Deborah Carr. The defects stem from many issues, including:

a. the use of polypropylene material in the Pelvic Mesh Products and the immune reaction that results;

b. the design of the Pelvic Mesh Products to be inserted transvaginally into an area of the body with high levels of pathogens that adhere to the mesh, which can cause immune reactions and subsequent tissue breakdown;

c. the contraction or shrinkage of the mesh;

d. biomechanical issues with the design of the mesh that creates strong amounts of friction between the mesh and the underlying tissue that subsequently causes that tissue to degrade;

e. the use and design of anchors in the Pelvic Mesh Products that when placed correctly are likely to pass through and injure major nerve routes in the pelvic region;

f. degradation of the mesh itself over time which causes the internal tissue to degrade;

g. the welding of the mesh itself during production, which creates a toxic substance that contributes to the degradation of the mesh and host tissue; and

h. the design of the trocars (devices used to insert the Pelvic Mesh Product into the vagina) requires tissue penetration in nerve-rich environments, which results frequently in the destruction of nerve endings.

34. Pelvic mesh products used for the surgical management of stress urinary incontinence (SUI) in women are primarily two different designs: the transobturator sling and the retropubic sling. The Obtryx at issue in this case is a transobturator sling. The transobturator sling passes into and through the obturator space into and through the obturator internus muscle in the groin.

35. Upon information and belief, Defendants have consistently underreported and withheld information about the propensity of the Pelvic Mesh Products, including the Obtryx and Y Mesh pelvic mesh products and their predicate devices, to fail and cause injury and complications, and have misrepresented the efficacy and safety of these products, through various means and media, actively and intentionally misleading the public.

36. Despite the chronic underreporting of adverse events associated with the Pelvic Mesh Products, enough complaints were recorded for the Food and Drug Administration ("FDA") to issue a public health notification regarding the dangers of these devices.

37. On October 20, 2008, the FDA issued a Public Health Notification that described over a thousand (1,000) complaints (otherwise known as "adverse events") that had been reported over a three-year period relating to the Pelvic Mesh Products and other similar products. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA's MAUDE database indicates that Defendants are seom of the manufacturers of the products that are the subject of the notification.

38. On July 13, 2011, the FDA issued a Safety Communication entitled, "UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse." Therein, the FDA advised that it had conducted an updated analysis of adverse events reported to the FDA and complications reported in the scientific literature and concluded

that surgical mesh used in transvaginal repair of pelvic organ prolapse was an area of **"continuing serious concern"** (emphasis added). The FDA concluded that serious complications associated with surgical mesh for transvaginal repair of pelvic organ prolapse were "not rare." These serious complications include, but are not limited to, neuromuscular problems, vaginal scarring/shrinkage, and emotional problems. Many of the serious complications required medical and surgical treatment and hospitalization. The FDA concluded that it was not clear that transvaginal repair of pelvic organ prolapse and stress urinary incontinence with mesh-kits was more effective than traditional non-mesh repair of these conditions. The FDA conducted a systematic review of the published scientific literature from 1996 to 2011 and concluded that transvaginal pelvic organ prolapse repair with mesh "does not improve symptomatic results or quality of life over traditional non mesh repair." In the July 13, 2011, Safety Communication, the FDA concluded that "a mesh procedure may put the patient at risk for requiring additional surgery or for the development of new complications. Removal of the mesh due to mesh complications may involve multiple surgeries and significantly impair the patient's quality of life. Complete removal of mesh may not be possible." The information contained in the FDA's Public Health Notification of October 2008 and the FDA Safety Communication of July 13, 2011, was known or knowable to Defendants and was not disclosed in any manner.

39. In September 2011, the FDA acknowledged the need for additional data and noted in "Surgical Mesh For Treatment of Women with Pelvic Organ Prolapse and Stress Urinary Incontinence" that the literature and information developing on SUI repair with mesh "indicates that serious complications can occur…[and] a case can be made for additional premarket and/or post market studies to better address the risk/benefit of all mesh products used for SUI."

40. After the 2011 FDA notification that mesh complications from POP repairs were "not rare," a 2013 article was published that stated: "as outlined in the FDA notifications, patients should be forewarned that some transvaginal mesh complications are life altering and might not always be surgically correctable. Furthermore, that study noted that "the women who received both MUS and TM represented a complicated surgical group. Fifteen women (43%) required MUS takedown concurrently with prolapse mesh excision. Two-thirds of these women had associated chronic pelvic pain and vaginal pain, in addition to their urinary symptoms."

41. Defendants did not, and have not, adequately studied the extent of the risks associated with their Pelvic Mesh Products.

42. In a December 2011 Joint Committee Opinion, the American College of Obstetricians and Gynecologists (ACOG) and the American Urogynecologic Society (AUGS) also identified physical and mechanical changes to the mesh inside the body as a serious complication associated with vaginal mesh, stating: There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh…Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable.

43. The ACOG/AUGS Joint Committee Opinion also recommended, among other things, that "[p]elvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk."

44. Plaintiff's injuries, as will be more fully established in Discovery, are reported in the FDA Safety Communication and in the ACOG/AUGS Joint Committee Opinion.

45. The FDA Safety Communication further indicated that the benefits of using

transvaginal mesh products instead of other feasible alternatives did not outweigh the associated risks. Specifically, the FDA Safety Communication stated: "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk."

46. Contemporaneously with the Safety Communication, the FDA released a publication titled "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse" (the White Paper). In the White Paper, the FDA noted that the published, peer-reviewed literature demonstrates that "[p]atients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh."

47. The FDA White Paper further stated that, "these products are associated with serious adverse events…compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair."

48. In its White Paper, the FDA advises doctors to, inter alia, "[r]ecognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications." The FDA concludes its White Paper by stating that it "has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse."

49. The FDA summarized its findings from its review of the adverse event reports and applicable literature stating that it "has NOT seen conclusive evidence that using transvaginal placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risk.

50. On April 16, 2019, the FDA ordered all manufacturers of surgical mesh intended for transvaginal repair of anterior compartment prolapse (cystocele) to stop selling and distributing their products immediately. In fact, the FDA has determined that the manufacturers, Boston Scientific and Coloplast specifically, have not demonstrated reasonable assurance of safety and effectiveness for these devices, which is the premarket standard that now applies to them since the agency reclassified them into class III (high risk) in 2016.[1]

51. Defendants knew about the Pelvic Mesh Products' risks and complications identified in the FDA Safety Communication, ACOG/AUGS Joint Committee Opinion, and the FDA Advisory that addressed the sales of transvaginal mesh implants for pelvic organ prolapse.

52. Defendants have further known the following:

a. that some of the predicate devices for the Pelvic Mesh Products had high failure and complication rates, resulting in the recall of some of these predicate devices;

b. that there were and are significant differences between the Pelvic Mesh Products and some or all of the predicate devices, rendering them unsuitable for designation as predicate devices;

c. that these significant differences render the disclosures to the FDA incomplete and misleading; and

d. that the Pelvic Mesh Products were and are causing numerous patients severe injuries and complications.

53. Defendants suppressed this information and failed to accurately and completely

[1] www.fda.gov/medical-devices/implants-and-prosthetics/urogynecologic-surgical-mesh-implants (last visited 6/18/2019) (last visited 06/15/2021).

disseminate or share this and other critical information with others, including Plaintiff. As a result, Defendants actively and intentionally misled and continues to mislead the public into believing that the Pelvic Mesh Products and the procedures for implantation were and are safe and effective.

54. Defendants failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Pelvic Mesh Products.

55. Defendants failed to design and establish a safe, effective procedure for removal of the Pelvic Mesh Products; thus, in the event of a failure, injury, or complications, it is impossible to easily and safely remove the Pelvic Mesh Products.

56. Feasible, reasonable, and suitable alternative designs as well as reasonable suitable alternative procedures and instruments for repair of stress urinary incontinence have existed at all times relevant to this matter, including, but not limited to the following: the Burch Procedure colposuspension with delayed absorbable sutures; autologous fascia slings; an allograft sling using a product like Repliform or other biological matrix; a sling with less polypropylene such as Ultrapro; a sling made with DynaMesh or other Polyvinylidene fluoride (PVDF) alternative, a retropubic sling, a retropubic mini-sling, such as the TFS device from TFS Surgical; or a retropubic sling or retropubic mini-sling comprised of a polymer-based alternative to polypropylene, such as DynaMesh or other Polyvinylidene fluoride (PVDF) alternative.

57. Feasible, reasonable, and suitable alternative designs as well as reasonable suitable alternative procedures for the repair of pelvic organ prolapse have existed at all times for the Y mesh relevant to this matter, including, but not limited to the following: native tissue repair, autologous rectus fascia sheath sacrocolpopexy, a mesh with less polypropylene such as Ultrapro, a mesh made with DynaMesh or other Polyvinylidene fluoride (PVDF) alternative.

58. The Pelvic Mesh Products were at all times utilized and implanted in a manner foreseeable to Defendants, as they generated the directions/instructions for use, created the procedures for implanting the devices, and trained the implanting physicians.

59. Defendants provided incomplete, insufficient, and misleading training and information to physicians to increase the number of physicians utilizing the Pelvic Mesh Products, and thus increase the sales of these products.

60. The Pelvic Mesh Products implanted into Plaintiff Deborah Carr were in the same or substantially similar condition as they were when they left the possession of Defendants, as well as being in the condition directed by and expected by Defendants.

61. Plaintiff Deborah Carr and her physician foreseeably used and implanted the Pelvic Mesh Products and did not misuse or alter these products in an unforeseeable manner.

62. The injuries, conditions, and complications suffered by women who have been implanted with the Pelvic Mesh Products include, but are not limited to, mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, acute and chronic nerve damage and pain, obturator nerve damage/neuralgia, pudendal nerve damage/neuralgia, pelvic floor damage, myofascial pain, chronic pelvic pain, urinary and fecal incontinence, and prolapse of organs. In many cases, these women have been forced to undergo intensive medical treatment, including, but not limited to, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and surgeries to remove portions of the female genitalia, to locate and remove mesh, and to attempt to repair pelvic organs, tissue, and nerve damage.

63. The medical and scientific literature studying the effects of polypropylene pelvic

mesh (like the material used in the Pelvic Mesh Products) have examined each of these injuries, conditions, and complications and determined that they are in fact casually related to the mesh itself and do not often implicate errors related to the implantation of the devices.

64. Defendants knew and had reason to know that the Pelvic Mesh Products could and would cause severe and grievous personal injury to the users of the Pelvic Mesh Products, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

65. At all relevant times herein, Defendants continued to promote the Pelvic Mesh Products as safe and effective even when no clinical trials had been done supporting long or short-term efficacy.

66. At all relevant times herein, Defendants failed to provide sufficient warnings and instructions that would have put the Plaintiff, her treating physicians, and the public on notice of the dangers and adverse effects caused by implantation of the Pelvic Mesh Products.

67. The Pelvic Mesh Products were defective as marketed due to inadequate warnings, instructions, labeling, and/or inadequate testing.

68. The Obtryx is designed to be inserted into and through the obturator internus muscle, producing a foreseeable risk of acute and chronic myofascial pain as well as a foreseeable risk of (1) obturator neuralgia, by virtue of its passage through the obturator internus muscle, and (2) pudendal neuralgia, by virtue of its passage through the obturator internus muscle which runs alongside the pudendal nerve as the pudendal nerve passes through Alcock's Canal. BSC failed to study or account for anatomic variations of the pudendal nerve when designing the device.

69. The Pelvic Mesh Products were designed to be permanently implanted into a

woman's body yet the product changes after implantation; it contracts over time which can pull or compress nerves important for sexual function, mobility, bowel function, bladder function, and chronic pelvic and nerve pain (neuralgia). This contraction over time, which can pull, and also cause fibrosis of muscles, adhesions between tissues, and inflammation which impair sexual function, impaired mobility, impaired bowel and bladder function, and chronic pelvic pain, neuralgia, among other mesh-related issues.

Defective Design

70. Defendants knew or should have known that their Pelvic Mesh Products, including the Obtryx and Y Mesh pelvic mesh products at issue in this case, unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks. At the time Defendants began marketing the Obtryx and Y Mesh, respectively, Defendants were aware that the Obtryx and Y Mesh were associated with each and every one of the adverse events communicated by the FDA in its July 13, 2011, safety communication.

71. The Obtryx and Y Mesh Pelvic Mesh Products were designed to be permanently implanted into a woman's body yet the products change after implantation; the mesh contracts over time which inter alia, can pull or compress nerves, muscles, and other soft tissues important for sexual function, mobility, bowel function, and bladder function. These product changes occur while the product is implanted.

72. Moreover, despite claims that polypropylene mesh is inert, the scientific evidence shows that this material as implanted in Plaintiff is biologically incompatible with human tissue and when used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair,

polypropylene and other surgical polymers promote a severe foreign body reaction and chronic inflammatory response in a large subset of the population implanted with Defendants' Pelvic Mesh Products, including the Obtryx and Y Mesh pelvic mesh products at issue herein. This "host defense response" by a woman's pelvic tissues promotes degradation of the polypropylene mesh and the pelvic tissue, causes chronic inflammation of the pelvic tissue, causes shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response and chronic pain, cause new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening and anatomic deformation, and can contribute to the formation of severe adverse reactions to the polypropylene mesh.

73. The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code." "Material Fragmentation" is defined as an "[i]ssue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction."

74. Defendants' Pelvic Mesh Products, including the Obtryx and Y Mesh pelvic mesh products at issue, were and are unreasonably susceptible to degradation and fragmentation inside the body, shrinkage or contraction inside the body, intense foreign body reaction, chronic inflammatory response, chronic wound healing, chronic infections in and around the mesh fibers, and nerve entrapment in the collagen scar formation. Defendants knew or should have known of these serious risks and should have, therefore, warned physicians and patients regarding these risks to the extent they were known or knowable.

75. To this day, the Obtryx and Y Mesh pelvic mesh products continue to be marketed

to the medical community and to patients as safe, effective, and reliable medical devices, implanted by safe, effective, and minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments and other competing products.

76. Defendants omitted and downplayed the risks, dangers, defects, and disadvantages of their Pelvic Mesh Products, including the Obtryx and Y Mesh pelvic mesh products at issue, and advertised, promoted, marketed, sold and distributed their Pelvic Mesh Products, including the Obtryx and Y Mesh pelvic mesh products at issue, as safe medical devices when Defendants knew or should have known that the Pelvic Mesh Products were not safe for their intended purposes, and that the products would cause, and did cause, serious medical problems, and in many patients, including Plaintiff, catastrophic injuries. Further, while some of the problems associated with the pelvic mesh products, including the Obtryx and Y Mesh Pelvic Mesh Products, were made known to physicians, the magnitude and frequency of these problems were not disclosed and were hidden from physicians.

77. Contrary to Defendants' representations and marketing to the medical community and to the patients themselves, their Pelvic Mesh Products, including the Obtryx and Y Mesh pelvic mesh products at issue, have high rates of failure, injury, and complications, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the Plaintiff, making them defective under the law.

78. Defendants failed to design and establish a safe, effective procedure for removal of their Pelvic Mesh Products, including the Obtryx and Y Mesh pelvic mesh products at issue, or to determine if a safe, effective procedure for removal of the Pelvic Mesh Products exists.

79. Feasible, suitable, and safer alternative designs to Defendants' Pelvic Mesh Products, have existed at all times relevant and in reasonable probability would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the products' utility. These safer alternative designs were economically and technologically feasible at the time the Pelvic Mesh products left the control of Defendants by the application of existing or reasonably achievable scientific knowledge. Safer alternatives designs for the Obtryx included but were not limited to: the Burch Procedure colposuspension with delayed absorbable sutures; autologous fascia slings; an allograft sling using a product like Repliform or other biological matrix; a sling with less polypropylene such as Ultrapro; a retropubic mini-sling, such as the TFS device from TFS Surgical; or a retropubic sling or retropubic mini-sling comprised of a polymer-based alternative to polypropylene, such as DynaMesh or other Polyvinylidene fluoride (PVDF) alternative. Safer alternative designs to the Y Mesh pelvic mesh product also existed, such as a device with less polypropylene such as Ultrapro or a polymer-based alternative to polypropylene, such as DynaMesh or other Polyvinylidene fluoride (PVDF) alternative.

80. The specific nature of defects for Defendants' Obtryx and Y Mesh pelvic mesh products at issue in this case include, but are not limited to, the following:

A. The use of polypropylene in the Pelvic Mesh Products and the adverse tissue reactions and host defense response that result from such material, causing adverse reactions and serious, permanent injuries including, but not limited to, painful recurrent erosions and associated intractable pain;

B. The design of the Obtryx and Y Mesh to be inserted into and through an area of the body that is blood vessel rich, nerve dense, and bacteria laden leading to excessive

blood loss and vascular damage, permanent nerve injury and associated chronic, intractable neuropathic pain, contaminated permanently-implanted mesh causing chronic infections, subclinical infections and biofilms, enhanced chronic inflammatory response, chronic wound healing with tissue destruction, as well as numerous other adverse reactions and serious and permanent injuries;

C. The use and design of arms and hooked anchors in the Obtryx sling, which, when placed in the women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;

D. The procedure to place the Obtryx sling requires blindly placing the arms the device through the obturator foramen that can injure major nerves that contribute to sexual function, contribute to mobility, and contribute to bowel and bladder function;

E. Biomechanical issues with the design of the Obtryx and Y Mesh which results in a non-anatomic condition leading to contraction or shrinkage of the mesh inside the body, that in turn causes surrounding tissue to become eroded, inflamed, fibrotic and infected, resulting in serious and permanent injury;

F. The propensity of the mesh design characteristics of the Obtryx and Y Mesh for plastic deformation when subjected to tension both during implantation and once implanted inside the body which causes the mesh, or portions thereof, to be encapsulated in a rigid scar plate which leads to nerve entrapment, bacterial entrapment, tissue destruction, enhanced inflammatory and fibrotic response and chronic pain;

G. The propensity of the mesh used in the Obtryx and Y Mesh to become rigid and inflexible, causing it to be improperly mated to the delicate and sensitive areas of the

vagina and pelvis where the product is implanted, and causing discomfort and pain with normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking);

H. The propensity of the mesh used in the Obtryx and Y Mesh for degradation or fragmentation over time, which causes an increased surface area that leads to enhanced chronic inflammatory and fibrotic reaction, causes a "barbed wire" or "saw blade" effect by the fragmented surface "sawing" through the tissue, leads to bacteria harboring in the fragmented, peeled and split fiber surface which in turn leads to chronic infections at the mesh surface, and results in continuing injury over time; and

I. The inability of surgeons to effectively treat many of these conditions due to the integration of the mesh into the pelvic tissue and thus the inability to safely remove or excise the mesh once a complication occurs.

Failure to Warn/Inadequate Warnings & Instructions

81. The Obtryx and Y Mesh are also defective due to Defendants' failure to adequately warn or instruct Plaintiff and/or her health care providers after the product left the manufacturer and before and after implantation of the Obtryx and Y Mesh of subjects including, but not limited to, the following:

A. The Pelvic Mesh Products' propensities to contract, retract, and/or shrink inside the body;

B. The Pelvic Mesh Products' propensities for degradation, fragmentation and/or migration;

C. The Pelvic Mesh Products' inelasticity preventing proper mating with the pelvic floor

and vaginal region;

D. The frequency and manner of transvaginal mesh erosion or extrusion resulting from the Pelvic Mesh Products;

E. The risk of chronic inflammation resulting from the Pelvic Mesh Products;

F. The risk of chronic infections resulting from the Pelvic Mesh Products;

G. The risk of permanent vaginal or pelvic scarring resulting from the Pelvic Mesh Products;

H. The risk of de novo urinary dysfunction resulting from the Pelvic Mesh Products;

I. The risk of de novo dyspareunia or painful sexual intercourse resulting from the Pelvic Mesh Products;

J. The risk of recurrent, intractable pelvic pain and other pain resulting from the Pelvic Mesh Products;

K. The need for corrective or revision surgery to adjust or remove the Pelvic Mesh Products which in some cases is not feasible nor possible;

L. The severity of complications that could arise as a result of implantation of the Pelvic Mesh Products;

M. The hazards associated with the Pelvic Mesh Products;

N. The Pelvic Mesh Products' defects described herein;

O. Treatment of stress urinary incontinence with BSC's Obtryx Pelvic Mesh Product is no more effective than feasible, available and safer alternatives;

P. Treatment of stress urinary incontinence with BSC's Obtryx Pelvic Mesh Product exposes patients to greater risk than feasible, available and safer alternatives;

Q. Treatment of stress urinary incontinence with BSC's Obtryx Pelvic Mesh Product makes future surgical repair more difficult than feasible, available and safer alternatives;

R. Use of the Pelvic Mesh Products puts the patient at greater risk of requiring additional surgery than feasible, available and safer alternatives;

S. Removal of the Pelvic Mesh Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life;

T. Complete removal of the Pelvic Mesh Products may not be possible and may not result in complete resolution of the complications, including pain; and

U. The nature, magnitude, and frequency of the complications that could arise as a result of implantation of the Pelvic Mesh Products.

82. Defendants underreported and continue to underreport information about the propensity of their Pelvic Mesh Products, including the Obtryx and Y Mesh pelvic mesh products at issue, to fail and cause injury and complications and have made unfounded representations regarding the efficacy and safety of the Pelvic Mesh Products through various means and media.

83. Defendants underreported and continue to underreport information about the propensity of their Pelvic Mesh Products, including the Obtryx and Y Mesh pelvic mesh products at issue, to fail and to cause injury and complications and have made unfounded representations regarding the efficacy and safety of their Pelvic Mesh Products including the Obtryx and Y Mesh pelvic mesh products at issue, through various means and media.

84. Defendants failed to perform proper and adequate testing and research in order to determine and evaluate the nature, magnitude and frequency of the risks attendant to their Pelvic

Mesh Products, including the Obtryx and Y Mesh pelvic mesh products at issue.

85. The Obtryx and Y Mesh pelvic mesh products at issue was at all times utilized and implanted in a manner intended and/or foreseeable to Defendants, as Defendants generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physician.

86. Defendants knowingly provided incomplete and insufficient training and information to physicians regarding the use of their Pelvic Mesh Products, including the Obtryx and Y Mesh pelvic mesh products at issue, and the aftercare of patients implanted with those Pelvic Mesh Products.

87. At all relevant times herein, Defendants continued to promote their products as safe and effective even when no clinical trials had been done supporting long-term or short-term efficacy or safety.

88. In doing so, Defendants failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with their Pelvic Mesh Products, including the magnitude and frequency of these risks.

89. At all relevant times herein, Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff, the medical community, Plaintiff's treating physicians, and the general public on notice of the dangers and adverse effects caused by implantation of the Defendants' Pelvic Mesh Products, including the Obtryx and Y Mesh pelvic mesh products at issue.

90. Defendants' Pelvic Mesh Products, including the Obtryx and Y Mesh pelvic mesh products at issue, as designed, manufactured, distributed, sold and/or supplied by Defendants,

were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendants' knowledge of lack of safety.

91. The risk of serious injuries was known or should have been known to Defendants, but in spite of these risks, Defendants continued to market the Obtryx and Y Mesh pelvic mesh products for transvaginal use to physicians and patients, including Plaintiff and Plaintiff's healthcare providers, without adequate warnings.

Resulting Injury from Defendants' Pelvic Mesh Products

92. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with Defendants' Pelvic Mesh Products include, but are not limited to: erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage/neuralgia, pelvic floor damage, chronic pelvic pain, emotional distress and mental anguish, and other debilitating complications. In addition, affected women, including Plaintiff, will need to be continuously monitored because of being implanted with Defendants' Pelvic Mesh Products.

93. In many of these cases, including that of the Plaintiff, women have had or will have to undergo extensive medical treatment, including, but not limited to, operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia. Removal of contracted, eroded and/or infected transvaginal mesh can require multiple surgical interventions for removal of mesh and results in scarring on fragile compromised pelvic tissue and muscles.

94. The medical and scientific literature studying the effects of pelvic mesh products, like that of the Obtryx and Y Mesh pelvic mesh products implanted in Plaintiff, has examined each of these injuries, conditions, and complications, and has reported that they are causally related to the pelvic mesh products.

FACTUAL BACKGROUND

Plaintiff's Obtryx & Y Mesh Implantation

95. Upon information and belief, Andrew Grollman, M.D. recommended the Pelvic Mesh Products to Plaintiff Deborah Carr as appropriate and safe for the treatment of her stress urinary incontinence and pelvic organ prolapse. Consequently, Plaintiff consented to the implantation of the Pelvic Mesh Products.

96. On August 29, 2019, Plaintiff Deborah Carr underwent surgery to address her stress urinary incontinence and pelvic organ prolapse at Lovelace Women's Hospital with Dr. Grollman. During this surgery, she was implanted with both a Boston Scientific Obtryx II Halo System as well as Coloplast Restorelle Y Mesh identified as follows:

Implants:

Implant Name	Type	Inv. Item	Serial No.	Manufacturer	Lot No.	LRB	No. Used
MESH SURGICAL RESTORELL E Y CONTOUR MERIDIAN VPS POLYPROPY LENE L24 CM X W3 CM STERILE LATEX FREE SACROCOLP OSUSPENSI ON SACROCOLP OPEXY - LOG1392084	Mesh	MESH SURGICAL RESTORELL E Y CONTOUR MERIDIAN VPS POLYPROPY LENE L24 CM X W3 CM STERILE LATEX FREE SACROCOLP OSUSPENSI ON SACROCOLP OPEXY		COLOPLAST CORP		N/A	1
SYSTEM URETHRAL SUPPORT BLUE 22CM .15MM OBTRYX II PRECISIONB LUE ADVANTAGE THK.66MM 1182UM MIDURETHR AL TRANSOBTU RATOR POLYPROPY LENE SLING HALO NEEDLE DILATOR LEG LOOP FEMALE STRESS	Sling	SYSTEM URETHRAL SUPPORT BLUE 22CM .15MM OBTRYX II PRECISIONB LUE ADVANTAGE THK.66MM 1182UM MIDURETHR AL TRANSOBTU RATOR POLYPROPY LENE SLING HALO NEEDLE DILATOR LEG LOOP FEMALE STRESS		BOSTON SCIENTIFIC CORP	22949 684	N/A	1

97. The Obtryx and Y Mesh devices implanted in Plaintiff were in the same or substantially similar condition as they were when they left Defendants' possession, and in the condition directed by and expected by Defendants. Plaintiff's treating physician implanted the Obtryx and Y Mesh devices properly and appropriately.

98. As a direct and proximate cause of having the Obtryx and Y Mesh devices implanted in her, Plaintiff Deborah Carr has experienced significant mental and physical pain and suffering, including erosion, dyspareunia, neuromuscular pain, pudendal neuralgia, disabling pelvic pain, abdominal pain, groin pain, recurrence of incontinence, perforation and vaginal

scarring, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

99. Plaintiff could not have reasonably discovered her injuries and/or the occasion, manner and/or means by which Defendants' breach of duty occurred until within three years of the filing of this complaint.

100. Further, Plaintiff did not and, exercising reasonable diligence, including consultation with medical professionals, could not discover the existence of her legal cause of action or the injuries caused by Defendants' breach of duty and/or defective products until within three years of the filing of this complaint. Further, Defendants continues to deny that their products are defective or cause injuries such as those suffered by Plaintiff and Defendants continued to manufacture and sell the products at issue and/or related or predicate products. Any applicable statute of limitations has been tolled by the knowing and active concealment and denial of material facts known by Defendants when Defendants had a duty to disclose and/or by the application of the discovery rule.

101. Neither Plaintiff nor her healthcare providers were warned that the Obtryx and Y Mesh devices were unreasonably dangerous or of the risks of the devices, outlined herein, even when used exactly as intended by Defendants. To the contrary, Defendants promoted and sold the type of transvaginal mesh devices implanted in Plaintiff and thousands of women like Plaintiff, to healthcare providers as a safe alternative to other procedures that did not incorporate the Defendants' products.

102. As a direct and proximate result of being surgically implanted with Defendants' unreasonably dangerous transvaginal mesh products, the Obtryx and Y Mesh devices, Plaintiff has suffered, and continues to suffer, debilitating injuries, including but not limited to the injuries listed above and, likely, nerve pain that may be permanent. Plaintiff brings this suit for damages related to those injuries.

DISCOVERY RULE AND TOLLING

103. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

104. To the extent further pleading be necessary, Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

105. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiff had been injured, the cause of the injury, .and the tortious nature of the wrongdoing that caused the injury.

106. Plaintiff could not have reasonably discovered the occasion, manner and/or means by which Defendants' breach of duty occurred until within three years of the filing of this complaint. Further, Plaintiff did not and, exercising reasonable diligence, including consultation with medical professionals, could not discover the existence of her legal cause of action or the injuries caused by Defendants' breach of duty and/or defective products until within three years of the filing of this complaint. Defendants continue to deny that their products are defective or

cause injuries such as those suffered by Plaintiff and Defendants continue to manufacture, market, and sell all or some of the products at issue. Any applicable statute of limitations has been tolled by the knowing and active concealment and denial of material facts known by Defendants when Defendants had a duty to disclose and/or by the application of the discovery rule.

107. The running of the statute of limitations in this cause is tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Plaintiff and her healthcare providers of the true risks associated with the Pelvic Mesh Products.

108. As a result of Defendants' fraudulent concealment, Plaintiff and her healthcare providers were unaware, and could not have known or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of Defendants.

FIRST CAUSE OF ACTION
[Negligence]

109. Plaintiff realleges and incorporates by reference each and every allegation of this Complaint as if each were set forth fully and completely herein.

110. At all times herein mentioned, Defendants were engaged in the business of researching, manufacturing, licensing, fabricating, designing, labeling, distributing, using, supplying, selling, marketing, warranting, packaging and advertising the Obtryx and Y Mesh pelvic mesh products at issue in this case.

111. Defendants owed to Plaintiff and the public a duty to act reasonably and to exercise ordinary care in pursuit of the activities mentioned above, and Defendants breached said duty of care.

112. At all times relevant hereto, Defendants owed to Plaintiff and the public a duty to act reasonably and to exercise ordinary care with respect to the safe, legal, and proper manufacture, license, design, formulation, distribution, production, processing, assembly, testing, inspection, research, marketing, labeling, packaging, preparation for use, issuance of warnings with respect to use, promotion, advertising, sale, and safety monitoring of the Obtryx and Y Mesh pelvic mesh products, and to adequately test and warn of the risk and dangers of the Obtryx and Y Mesh pelvic mesh products, both before and after sale.

113. Additionally, Defendants owed to Plaintiff and the public a duty to provide accurate, reliable, and completely truthful information regarding the safety and any dangerous propensities of the Obtryx manufactured, used, distributed, and/or supplied by them and to provide accurate, reliable, and completely truthful information regarding the failure of the Obtryx and Y Mesh pelvic mesh products to perform as intended or as an ordinary consumer would expect.

114. Defendants further breached their duty of care in the testing of their Pelvic Mesh Products, including the Obtryx and Y Mesh pelvic mesh products at issue in this case, by failing to conduct adequate testing to ensure that the Pelvic Mesh Products were reasonably safe for implantation in the female pelvic area prior to releasing the Pelvic Mesh Products into the market, failing to conduct post-launch testing following adverse findings in the scientific and medical literature, and by failing to conduct post-launch testing to investigate and evaluate reports in the FDA adverse event databases for their potential significance for Defendants' Pelvic Mesh Products, including the Obtryx and Y Mesh pelvic mesh products at issue in this case.

115. Defendants breached the duty to take all reasonable steps necessary to manufacture and sell products that were not defective or unreasonably dangerous to consumers and users of the

products, including Plaintiff herein. Defendants were negligent in failing to use reasonable care as described herein in designing, manufacturing, marketing, labeling, packaging and selling the Pelvic Mesh Products at issue herein. Defendants breached the aforementioned duties in that Defendants negligently and carelessly designed, licensed, inspected or failed to inspect, tested or failed to test, inadequately warned or failed to warn of the health hazards, labeled, distributed, handled, used, supplied, sold, marketed, warranted, packaged, promoted, and advertised the Obtryx and Y Mesh pelvic mesh products in that said Obtryx and Y Mesh pelvic mesh products caused, directly and proximately, the injuries of Plaintiff through failure of the Obtryx and Y Mesh pelvic mesh products to perform as intended or as an ordinary consumer would expect. Defendants breached the aforementioned duty by, among other things:

a. Failing to design the Pelvic Mesh Products at issue herein so as to avoid an unreasonable risk of harm to women in whom the Pelvic Mesh Products at issue herein was implanted, including Plaintiff;

b. Failing to manufacture the Pelvic Mesh Products at issue herein so as to avoid an unreasonable risk of harm to women in whom the Pelvic Mesh Products at issue herein were implanted, including Plaintiff;

c. Failing to use reasonable care in the testing of the Pelvic Mesh Products at issue herein so as to avoid an unreasonable risk of harm to women in whom the Pelvic Mesh Products at issue herein was implanted, including Plaintiff;

d. Failing to use reasonable care in inspecting the Pelvic Mesh Products at issue herein so as to avoid an unreasonable risk of harm to women in whom the Pelvic Mesh Products at issue herein was implanted, including Plaintiff;

e. Failing to use reasonable care in the training and instruction to physicians for the safe use of the Pelvic Mesh Products at issue herein;

f. Failing to use reasonable care in studying the Pelvic Mesh Products at issue herein to evaluate their safety and to determine the nature, magnitude, and frequency of serious, life threatening complications that were known or knowable; and

g. Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the Pelvic Mesh Products at issue herein.

116. Defendants also negligently failed to warn or instruct Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

a. The use of polypropylene and/or collagen material in the Pelvic Mesh Products at issue herein and the immune reaction that results from such material, causing adverse reactions and injuries;

b. The design of the Pelvic Mesh Products at issue herein to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. Biomechanical issues with the design of the Pelvic Mesh Products at issue herein, including, but not limited to, the propensity of the Pelvic Mesh Products at issue herein to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. The use and design of arms and anchors in the Pelvic Mesh Products at issue herein, which, when placed in women, such as Plaintiff, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. The propensity of the Pelvic Mesh Products at issue herein for "creep," or to gradually elongate and deform when subjected to prolonged tension inside the body;

f. The inelasticity of the Pelvic Mesh Products at issue herein, causing it to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);

g. The propensity of the Pelvic Mesh Products at issue herein for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i. The propensity of the collagen products to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j. The adverse tissue reactions caused by the products, which are causally related to infection, as the polypropylene is a foreign material; and

k. The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanted according to

the manufacturers' instructions.

117. Defendants also negligently failed to warn or instruct Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

a. The Pelvic Mesh Products' propensities to contract, retract, and/or shrink inside the body;

b. The Pelvic Mesh Products' propensities for degradation, fragmentation and/or creep;

c. The Pelvic Mesh Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. The rate and manner of mesh erosion or extrusion;

e. The risk of chronic inflammation resulting from the Pelvic Mesh Products at issue herein;

f. The risk of chronic infections resulting from the Pelvic Mesh Products at issue herein;

g. The risk of permanent vaginal or pelvic scarring as a result of the Pelvic Mesh Products at issue herein;

h. The risk of recurrent, intractable pelvic pain and other pain resulting from the Pelvic Mesh Products at issue herein;

i. The need for corrective or revision surgery to adjust or remove the Pelvic Mesh Products at issue herein;

j. The severity of complications that could arise as a result of implantation of the Pelvic Mesh Products at issue herein including permanent nerve damage;

k. The hazards associated with the Pelvic Mesh Products at issue herein;

l. The Pelvic Mesh Products' defects described herein;

m. Treatment of stress urinary incontinence with the Pelvic Mesh Products at issue herein is no more effective than feasible available alternatives;

n. Treatment of stress urinary incontinence with the Pelvic Mesh Products at issue herein exposes patients to greater risk than feasible available alternatives;

o. Treatment of stress urinary incontinence with the Pelvic Mesh Products at issue herein makes future surgical repair more difficult than feasible available alternatives;

p. Use of the Pelvic Mesh Products at issue herein puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. Removal of the Pelvic Mesh Products at issue herein due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. Complete removal of the Pelvic Mesh Products at issue herein may not be possible and may not result in complete resolution of the complications, including pain.

118. As a proximate result of Defendants' negligent design, marketing, and testing of their Pelvic Mesh Products, including the Obtryx and Y Mesh pelvic mesh products at issue in this case, Plaintiff has been injured catastrophically, sustained severe and permanent pain, suffering, disability, impairment of mobility, impairment of sexual function, impairment of bowel and bladder function, loss of enjoyment of life, and economic damages.

119. By reason of the foregoing, Plaintiff has sustained damages in an amount in excess of the jurisdiction limits of all the lower courts which would have had jurisdiction.

120. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages, for punitive damages, and for costs in excess of $75,000 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

SECOND CAUSE OF ACTION
[Strict Liability: Design]

121. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

122. Additionally, or in the alternative, if same be necessary, Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

123. Defendants were and are engaged in the business of selling their respective pelvic mesh products, including the Obtryx and Y Mesh pelvic mesh products, in the State of New Mexico.

124. Defendants are manufacturers and/or suppliers of Pelvic Mesh Products, specifically the Obtryx and Y Mesh pelvic mesh products, and are strictly liable to Plaintiff for designing, creating, manufacturing, distributing, selling and placing their Pelvic Mesh Products, specifically the Obtryx and Y Mesh pelvic mesh products, into the stream of commerce.

125. The pelvic mesh products at issue herein, the Obtryx and Y Mesh pelvic mesh products, were respectively designed, marketed, manufactured and distributed by Defendants and were defective and not reasonably safe due to their improper, inadequate, and defective design.

126. The Obtryx and Y Mesh pelvic mesh products manufactured, designed, marketed, promoted, and sold by Defendants were expected to, and did, reach Plaintiff without substantial change in the condition in which they was sold and in the condition directed by and expected by Defendants. The Obtryx and Y Mesh pelvic mesh products were defective at the time of manufacture, development, design, production, testing, inspection, endorsement, prescription, sale and distribution, and at the time they left the possession of the Defendants.

127. Defendants designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the Pelvic Mesh Products at issue herein and Plaintiff was an expected user or consumer of the mesh products.

128. Defendants' Pelvic Mesh Products, including the Obtryx and Y Mesh pelvic mesh products at issue in this case, were defectively and improperly designed, rendering the products deficient and unreasonably dangerous and hazardous to Plaintiff.

129. The Pelvic Mesh Products at issue herein that were implanted in Plaintiff were conveyed in a condition not contemplated by reasonable persons among those considered expected users or consumers of the pelvic mesh products, like Plaintiff.

130. Defendants' Pelvic Mesh Products, specifically the Obtryx and Y Mesh pelvic mesh products, manufactured and/or supplied by Defendants, were defective in design or formulation in that, when they left the hands of Defendants, and they were unreasonably dangerous, taking into consideration the utility of these products and the risks involved in their use.

131. The pelvic mesh products at issue herein that were implanted in Plaintiff were, at the time conveyed, not in conformity with the generally recognized state of the art applicable to

the safety of the products at the time the products were designed, manufactured, packaged, labeled and/or sold. There were also safer alternative designs for the devices.

132. The pelvic mesh products at issue herein that were implanted in Plaintiff were not reasonably safe for their intended uses and were defective as described herein with respect to their design. These design defects include, but are not limited to, the following:

a. The use of polypropylene in the Obtryx and Y Mesh pelvic mesh products and the foreseeable adverse tissue reactions, host defense response, and immune reactions that result from such material leading to ongoing degradation of the mesh, shrinkage, perpetual scarification as the mesh degrades all of which have potential to produce adverse reactions and permanent injuries including but not limited to painful recurrent erosions, direct muscle and soft tissue injury, nerve entrapment or irritation of adjacent nerves, and associated intractable neuropathic pain and myofascial pain;

b. The design of the Obtryx and Y Mesh pelvic mesh products to be inserted into and through an area of the body that is blood vessel rich, nerve dense, and bacteria laden leading to excessive blood loss and vascular damage, permanent nerve injury and associated chronic, intractable neuropathic pain, contaminated permanently-implanted mesh causing chronic infections, subclinical infections and biofilms, enhanced chronic inflammatory response, chronic wound healing with tissue destruction, as well as numerous other adverse reactions and serious and permanent injuries without producing any additional therapeutic benefit when compared to other surgical treatment options for SUI;

c. The design of the Obtryx to be inserted into and through the levator muscles produces a foreseeable risk of acute and chronic myofascial pain;

d. The design of the Obtryx to be inserted into and through the obturator internus muscles produces a foreseeable risk of obturator and pudendal neuralgia that may present acutely or months to years after implantation;

f. The design of the Obtryx and Y Mesh to be inserted into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries without producing any additional therapeutic benefit when compared to other surgical treatment options for SUI/POP;

g. Biomechanical issues with the design of the Obtryx and Y Mesh pelvic mesh products, including, but not limited to, the propensity of the mesh in the Obtryx and Y Mesh pelvic mesh products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in serious and permanent injury to the soft tissues and muscles of the pelvic floor without producing any additional therapeutic benefit when compared to other surgical treatment options for SUI;

h. The use and design of arms and anchors in the Obtryx device at issue herein, which, when placed in women, such as Plaintiff, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

i. The propensity of the Pelvic Mesh Products at issue herein for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

j. The inelasticity of the Obtryx and Y Mesh products, causing the products to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g. intercourse, defecation, or walking) without providing any additional therapeutic benefit when compared to other surgical treatment options for SUI/POP:

k. The propensity of the mesh in the Obtryx and Y Mesh pelvic mesh products to degrade or fragment over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time; and

l. The hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

m. The propensity of the mesh in the Obtryx and Y Mesh pelvic mesh products to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

n. The hardening of the Pelvic Mesh Products at issue herein in the body;

o. The creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions that are unique to polypropylene without providing any additional therapeutic benefit when compared to other non-polypropylene surgical treatment options for SUI/POP;

p. The use of polypropylene material in the Pelvic Mesh Products at issue herein and the failure to provide adequate directions for use ("DFU") or instructions for use ("IFU") and training.

133. As designed, Defendants' Pelvic Mesh Products, including the Obtryx and Y Mesh pelvic mesh products at issue in this case, were and are inherently dangerous and defective, unfit and unsafe for their intended and reasonably foreseeable uses, and do not meet or perform to the expectations of patients and their healthcare providers.

134. Defendants' Pelvic Mesh Products, including the Obtryx and Y Mesh pelvic mesh products at issue in this case, create risks to the health and safety of the patients that are far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of the Pelvic Mesh Products.

135. Defendants' Pelvic Mesh Products, including the Obtryx and Y Mesh pelvic mesh products at issue in this case, are not reasonably safe and so likely to be harmful to users that a reasonable person who had actual knowledge of their potential for producing injury would conclude that it should not have been marketed.

136. Defendants' Pelvic Mesh Products, including the Obtryx and Y Mesh pelvic mesh products at issue in this case, are dangerous beyond that which would be contemplated by an ordinary person, doctor, or patient with the ordinary knowledge common to the community as to its characteristics.

137. Defendants have intentionally and recklessly designed, marketed, labeled, sold, and distributed their Pelvic Mesh Products (including the Obtryx and Y Mesh pelvic mesh products at issue in this case) with wanton and willful disregard for the rights and health of Plaintiff, and with malice, placing their economic interests above the health and safety of Plaintiff.

138. At all relevant times, feasible, safer mesh-related alternative designs to the Obtryx pelvic mesh product existed, such as the Burch Procedure colposuspension with delayed absorbable sutures; autologous fascia slings; an allograft sling using a product like Repliform or other biological matrix; a sling with less polypropylene such as Ultrapro; a retropubic mini-sling, such as the TFS device from TFS Surgical; or a retropubic sling or retropubic mini-sling comprised of a polymer-based alternative to polypropylene, such as Polyvinylidene fluoride (PVDF). At all relevant times, feasible, safer mesh-related alternative designs to the Y Mesh pelvic mesh product existed, such as a device with less polypropylene such as Ultrapro or a polymer-based alternative to polypropylene, such as DynaMesh or other Polyvinylidene fluoride (PVDF) alternative.

139. With respect to Plaintiff in particular, flaws with the Obtryx and Y Mesh pelvic mesh products' design, including but not limited to the use of polypropylene mesh in the Obtryx and Y Mesh pelvic mesh products, the weight and pore size of the polypropylene mesh used in the Obtryx and Y Mesh pelvic mesh products, and the transobturator design of the Obtryx device[2], caused and created chronic inflammation and chronic foreign body reaction inside of Plaintiff, as well entrapment, aggravation, irritation and/or compression of Plaintiff's obturator, pudendal, and/or ilioinguinal nerves, which in turn damaged and aggravated the surrounding soft tissues. As a direct and proximate result of these design flaws, Plaintiff has suffered and in all reasonable probability will continue to suffer from dyspareunia, neuromuscular pain, pudendal neuralgia, pelvic pain, groin pain, vaginal pain, thigh pain, perineal pain, paresthesia, depression, and impaired bladder function, as well as other symptoms and damages, including severe and permanent pain, suffering, disability, impairment of mobility, impairment of sexual function, impairment of bowel and bladder function, loss of enjoyment of life, and economic damages.

140. As a direct and proximate result of the wrongful acts and omissions of Defendants, Plaintiff suffered severe injuries, emotional distress, and economic damages for which she now seeks compensation.

141. By reason of the foregoing, Plaintiff has sustained damages in an amount in excess of the jurisdiction limits of all the lower courts which would have had jurisdiction.

[2] As stated previously, the transobturator design of the Obtryx requires it be inserted into and through the obturator internus muscle, producing a foreseeable risk of acute and chronic myofascial pain as well as a foreseeable risk of: (1) obturator neuralgia, by virtue of its passage through the obturator internus muscle, and (2) pudendal neuralgia, by virtue of its passage through the obturator internus muscle which runs alongside the pudendal nerve as the pudendal nerve passes through Alcock's Canal.

142. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages, for punitive damages, and for costs in excess of $75,000 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

THIRD CAUSE OF ACTION
[Strict Liability: Marketing/Failure to Warn]

143. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

144. Defendants supplied the Obtryx and Y Mesh pelvic mesh products that were implanted in Plaintiff.

145. Defendants designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold, supplied, and/or distributed the Pelvic Mesh Product at issue herein.

146. The Obtryx and Y Mesh pelvic mesh products were manufactured, designed, marketed, labeled and sold in a defective condition, for use by the Plaintiff's physicians and/or healthcare providers and all other consumers of the products, making the products unreasonably dangerous.

147. Defendants' Obtryx and Y Mesh pelvic mesh products are defective due to Defendants' failure to adequately warn or instruct Plaintiff and/or her health care providers of subjects.

148. In their directions/instructions for use, as well as the marketing materials they prepared and disseminated to patients and healthcare providers, Defendants omitted critical information regarding the risks and potential complications of the Obtryx and Y Mesh pelvic mesh products at issue in this case. Specifically, Defendants failed to properly and adequately warn and

instruct Plaintiff and her healthcare providers as to the following (subsequently referred to as the "Risks and Potential Complications"):

a. That the Obtryx and Y Mesh pelvic mesh products were not studied prior to launch for safety and efficacy;

b. That the Obtryx and Y Mesh pelvic mesh products have propensities to contract, retract, and/or shrink inside the body;

c. That the Obtryx and Y Mesh pelvic mesh products have propensities for degradation, fragmentation, and/or creep;

d. That the Obtryx and Y Mesh pelvic mesh products' inelasticity prevents proper mating with the pelvic floor and vaginal region;

e. The magnitude of the risk of mesh erosion or extrusion;

f. The risk of chronic inflammation resulting from the Obtryx and Y Mesh pelvic mesh products;

g. The risk of chronic infections resulting from the Obtryx and Y Mesh pelvic mesh products;

h. The risk of developing chronic regional pain syndrome as a result of chronic inflammation/infection;

i. The risk of permanent vaginal or pelvic scarring as a result of the Obtryx and Y Mesh pelvic mesh products;

j. The risk of recurrent, intractable pelvic pain, nerve pain, and other pain resulting from the Obtryx and Y Mesh pelvic mesh products;

k. The risk of direct nerve injury to the obturator nerve;

l. The risk of secondary nerve irritation to the obturator nerve;

m. The risk of secondary nerve irritation to the pudendal nerve;

n. The magnitude of the risk of dyspareunia (painful sexual intercourse) in patients;

o. That the Obtryx and Y Mesh pelvic mesh products may result in dyspareunia that makes vaginal penetration impossible;

p. The frequency with which the need for corrective or revision surgery to adjust or remove the Obtryx and Y Mesh pelvic mesh products may occur in patients;

q. The magnitude of the risk of acute and long-term complications that could arise as a result of implantation of the Obtryx and Y Mesh pelvic mesh products in patients;

r. The hazards associated with the Obtryx and Y Mesh pelvic mesh products, including obturator, pudendal, and ilioinguinal neuralgia, permanent nerve damage, and pelvic floor and groin myalgia;

s. That treatment of SUI/POP with the Pelvic Mesh Products exposes patients to greater risk than feasible available devices for SUI/POP, including pelvic mesh products utilizing alternative polypropylene material or non-polypropylene surgical products, alternatives, and procedures;

t. That treatment with the Obtryx and Y Mesh pelvic mesh products makes future surgical repair more difficult than feasible available alternatives;

u. That the Obtryx and/or Y Mesh products offers no improvement in efficacy compared to non-mesh repairs and non-mesh repairs do not place the obturator or pudendal nerve at risk acutely or over time;

v. That use of the Obtryx and Y Mesh pelvic mesh products put the patient at greater risk of requiring additional surgery than feasible available alternatives;

w. That removal of the Obtryx and Y Mesh pelvic mesh products due to complications may significantly impair the patient's quality of life;

x. That complete removal of the Obtryx and Y Mesh pelvic mesh products may not be possible;

y. That complete removal of the Obtryx and Y Mesh pelvic mesh products may not result in complete resolution of the complications, including pain;

z. The foreseeable and unavoidable risk of acute obturator, pudendal, and/or ilioinguinal neuralgia or obturator, pudendal, and/or ilioinguinal neuralgia occurring months or years after implantation;

aa. The magnitude of the risk of obturator and/or pudendal neuralgia; and

bb. The risk of permanent injury and pain to the muscles and soft tissues of the pelvic floor that may occur acutely after implantation or become symptomatic months or years after implantation.

149. Arguing further, Defendants failed to properly and adequately warn and instruct Plaintiff and her healthcare providers as to the proper candidates for, and the safest and most effective methods of, implantation and use of Defendants' Pelvic Mesh Products, including the Obtryx and Y Mesh pelvic mesh products at issue in this case. Defendants also failed to properly and adequately warn and instruct Plaintiff and her healthcare providers with regard to the inadequate research and testing of the Pelvic Mesh Products, including the Obtryx and Y Mesh pelvic mesh products at issue in this case, and the complete lack of a safe, effective procedure for removal of the Pelvic Mesh Products. Defendants intentionally, recklessly, and maliciously misrepresented the safety, risks, and benefits of Defendants' Pelvic Mesh Products, including the Obtryx and Y Mesh pelvic mesh products at issue in this case, understating the risks and

exaggerating the benefits in order to advance its own financial interests, with wanton and willful disregard for Plaintiff's rights and health.

150. Had Defendants properly and adequately warned and instructed Plaintiff and her healthcare providers with regarding to the Obtryx and Y Mesh pelvic mesh products' Risks and Potential Complications, upon information and belief, Plaintiff would not have been recommended implantation of the Obtryx and Y Mesh pelvic mesh products, and Plaintiff would not have proceeded with implantation of the Obtryx and Y Mesh pelvic mesh products, thus avoiding the injuries Plaintiff has alleged herein.

151. As a proximate result of Defendants' design, manufacture, labeling, marketing, sale, and distribution of the Pelvic Mesh Products, including the Obtryx and Y Mesh pelvic mesh products at issue in this case, Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, impairment of mobility, impairment of sexual function, impairment of bowel and bladder function, loss of enjoyment of life, and economic damages.

152. Defendants, by exercising reasonable diligence, could have made such warnings available to Plaintiff, Plaintiff's healthcare providers, and the medical community.

153. As a direct and proximate result of Defendants' failure to provide Plaintiff, Plaintiff's healthcare providers, and the medical community with sufficient or adequate warnings, Plaintiff and Plaintiff's healthcare providers were not adequately informed of the potential dangers and/or defects of the Pelvic Mesh Products at issue herein.

154. As a direct and proximate result of the wrongful acts and omissions of Defendants, Plaintiff suffered severe injuries, emotional distress, and economic damages.

155. By reason of the foregoing, Plaintiff has sustained damages in an amount in excess of the jurisdiction limits of all the lower courts which would have had jurisdiction.

156. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages, for punitive damages, and for costs in excess of $75,000 and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

FOURTH CAUSE OF ACTION
[Negligent Misrepresentation]

157. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

158. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, and the public, that the Pelvic Mesh Products had not been adequately tested and found to be safe and effective for the treatment of incontinence and prolapse. The representations made by Defendants, in fact, were false.

159. Defendants failed to exercise ordinary care in the representations concerning the Pelvic Mesh Products while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented the Pelvic Mesh Products' high risk of unreasonable, dangerous, adverse side effects.

160. Defendants breached their duty in representing that the Defendants' Pelvic Mesh Product has no serious side effects different from older generations of similar products and/or procedures to Plaintiff, Plaintiff's physicians, and the medical and healthcare community.

161. As a foreseeable, direct and proximate result of the negligent misrepresentation of Defendants as set forth herein, Defendants knew, and had reason to know, that the Pelvic Mesh

Product had been insufficiently tested, or had not been tested at all, and that it lacked adequate and accurate warnings, and that it created a high risk, and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects, including, erosion, pain and suffering, surgery to remove the products, and other severe and personal injuries, which are permanent and lasting in nature.

162. As proximate result of the Defendants' conduct, Plaintiff has been injured, often catastrophically, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, and economic damages.

163. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

DAMAGES

164. Plaintiff realleges and incorporates by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

General and Special Damages

165. As a direct and proximate result of having the Obtryx and Y Mesh pelvic mesh products implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury which includes or more likely than not may include, inter alia, any of the following: erosion, neuromuscular pain, pudendal neuralgia, pelvic pain, groin pain, thigh pain, recurrent urinary tract infections, chronic dyspareunia, and bladder dysfunction, will likely undergo medical treatment and procedures, has suffered financial or

economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

166. Plaintiff's injuries, as will be more fully established in discovery, are of the exact type reported in the FDA Safety Communication and in the ACOG/AUGS Joint Committee Opinion.

167. The injuries suffered by Plaintiff were caused by the wrongful acts and omissions of Defendants.

Exemplary Damages

168. At all times relevant herein, Defendants:

a. Knew that their Pelvic Mesh Products, including the Obtryx and Y Mesh pelvic mesh products, were dangerous, ineffective, and caused significant, life-altering complications and side-effects;

b. Concealed the dangers and health risks from Plaintiff, physicians, hospitals, other medical providers, the FDA, its users and the public at large;

c. Made misrepresentations to Plaintiff, physicians, hospitals, other medical providers, their users and the public at large as to the safety and efficacy of their Pelvic Mesh Products, including the Obtryx and Y Mesh pelvic mesh products; and

d. With full knowledge of the health risks associated with their Pelvic Mesh Products, including the Obtryx and Y Mesh pelvic mesh products, and without adequate warnings of the same, manufactured, designed, marketed, promoted, developed, sold and/or distributed their Pelvic Mesh Products,

including the Obtryx and Y Mesh pelvic mesh products, for routine use.

169. Defendants, by and through their officers, directors, managing agents, authorized sales representatives, employees and/or other agents engaged in acts and/or omissions involving subjective awareness of an extreme degree of risk, indicating conscious indifference to the rights, safety, or welfare of others. As such, the conduct of Defendants warrants the imposition of exemplary damages under all applicable legal standards.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands trial by jury, and pray for judgment against Defendants as follows:

1. A judgment against Defendants Boston Scientific Corporation and Coloplast Corporation holding them liable for compensatory damages in a reasonable amount determined to be fair and just by the jury in this cause sufficient to adequately compensate Plaintiff for her harms and losses, including but not limited to damages:

a. For past and future general damages, the exact amount of which has yet to be ascertained, in an amount which will conform to proof at time of trial;

b. For past and future economic and special damages, according to proof at the time of trial;

c. For past and future medical and incidental expenses, according to proof at the time of trial;

d. For past and future loss of earnings and impaired earning capacity, according to proof at the time of trial;

e. For past and future physical impairment;

f. For past and future physical disfigurement; and

g. For past and future pain and suffering, as well as mental and emotional distress, according to proof at the time of trial.

2. For punitive and exemplary damages in a reasonable amount determined to be fair and just by the jury;

3. For costs, attorneys' fees, interest, or any other relief, monetary or equitable, to which she is entitled; and

4. For such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury as to all issues in the above captioned matter.

Date: August 9, 2022

Respectfully submitted,

/s/ Keith E. Patton
KEITH E. PATTON
PATTON LAW, P.C.
New Mexico Bar No. 148510
Texas Bar No. 24032821
500 Copper Ave NW, Suite 100
Albuquerque, NM 87102
Phone: 505-910-4800
Fax: 505-910-4382
keith@pattonlaw.com

BEN C. MARTIN
Texas Bar No. 13052400
(*pro hac vice* to be filed)
LAURA J. BAUGHMAN
(*pro hac vice* to be filed)
Texas Bar No. 00791846
RACHEL L. WRIGHT
(*pro hac vice* to be filed)
MARTIN BAUGHMAN, PLLC
3141 Hood Street, Level 6
Dallas, TX 75219

Office: 214.761.6614
Fax: 214.744.7590
bmartin@martinbaughman.com
lbaughman@martinbaughman.com
rwright@martinbaughman.com

ATTORNEYS FOR PLAINTIFF